

New Steps Aimed at Cutting Risks from Acetaminophen

The Food and Drug Administration (FDA) has taken new steps to reduce the risk of severe liver injury associated with acetaminophen, a widely used pain- and fever-reducing drug.

On Jan. 13, 2011, FDA announced it is

- asking all makers of prescription products that contain acetaminophen to limit the amount of the drug to 325 milligrams per tablet or capsule
- requiring a Boxed Warning on all prescription acetaminophen products that highlights the potential risk for severe liver injury. Boxed Warnings are FDA's strongest warnings for prescription drug products, used for calling attention to serious or life-threatening risks

In addition, FDA is requiring a Warning on labels of all prescription products that contain acetaminophen that highlights the potential for allergic reactions. These allergic reactions include swelling of the face, mouth, and throat; difficulty breathing; itching; and rash.

Used effectively in both prescription and over-the-counter (OTC) products, acetaminophen is among the most commonly used drugs in the United States.

Also called APAP, acetaminophen is used in many prescription products in combination with other drugs, usually opioids such as codeine (Tylenol with



Codeine), oxycodone (Percocet), and hydrocodone (Vicodin). Examples of other prescription acetaminophen combination products may be found in the List of Marketed Acetaminophen-Containing Prescription Products, available online at www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm239874.htm.

Reports of Severe Liver Injury

FDA continues to receive reports of severe liver injury associated with the use of products that contain acetaminophen.

Sandra Kweder, M.D., deputy director of FDA's Office of New Drugs, says the agency's most recent action is aimed at making pain medications containing acetaminophen safer for patients to use.

"Overdoses from prescription products containing acetaminophen

account for nearly half of all cases of acetaminophen-related liver failure in the U.S., many of which result in liver transplant or death," says Kweder.

Most of the cases of severe liver injury occurred in patients who

- took more than the prescribed dose of an acetaminophen-containing product in a 24-hour period
- took more than one acetaminophen-containing product at the same time
- drank alcohol while taking the drug

"There is no immediate danger to patients who take these combination pain medications and they should continue to take them as directed by their health care provider," says Kweder. "The risk of liver injury primarily occurs when patients take multiple products containing acetaminophen at one time and exceed

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the current maximum dose of 4,000 milligrams within a 24-hour period.”

OTC Products Already Require Warnings

Over-the-counter (OTC) pain and fever medications, such as Tylenol, that contain acetaminophen are already required to change the dosage labeling to include information about the potential for safety risks, including liver injury. In addition, FDA continues to evaluate ways to reduce the risk of acetaminophen-related liver injury from OTC products.

In its January 2011 announcement, FDA emphasized that combination products that contain 325 milligrams of acetaminophen (or less) per dosage unit are effective for treating pain.

The new dosage limit will not affect other aspects of prescribing acetaminophen combination products. The number of tablets, capsules, or other dosage units that may be prescribed and the time intervals at which they may be prescribed will not change.

In addition, the new action will be phased in over three years. Thus, prescription pain medications containing acetaminophen will continue to be available during the transition.

Steps You Can Take

Do not stop taking your prescription pain medicine unless told to do so by your health care professional.

FDA says you can help reduce the

risk of adverse effects from acetaminophen by

- taking opioid/acetaminophen combination products only as prescribed by a health care professional
- not taking more of an acetaminophen-containing medicine than directed
- carefully reading all labels for prescription and OTC medicines and asking the pharmacist if your prescription pain medicine contains acetaminophen
- not taking more than one product that contains acetaminophen at any given time
- not drinking alcohol when taking acetaminophen
- stopping your medicine and seeking medical help immediately if you
 - experience allergic reactions such as swelling of the face, mouth, and throat; difficulty breathing; itching; or rash
 - think you have taken more acetaminophen than directed
- not taking more acetaminophen than the maximum daily dose of 4,000 milligrams (4 grams)
- not trying to calculate the total amount of acetaminophen you take each day. Instead, talk to your health care professional about all of the medications—prescription and OTC—you are taking and which include acetaminophen

In addition, you can report any side effects from the use of products containing acetaminophen to FDA's MedWatch Adverse Event Reporting Program online (www.fda.gov/Safety/MedWatch) or by mail, fax, or phone.

- Regular Mail: Use postage-paid, pre-addressed FDA form 3500
- Fax: 1-800-FDA-0178
- Phone: 1-800-332-1088

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